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June 27, 2022

VIA ECF

The Hon. Robert J. Kugler
United States District Judge
USDJ, District of New Jersey
Mitchell H. Cohen Building & U.S.
Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Special Master the Hon. Thomas
Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th
Floor
Philadelphia, PA 19103

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK-KMW (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' position with respect to the agenda topics for the conference with the Court on June 29, 2022. Defendants do not expect the need to discuss any confidential materials as part of these agenda items, but reserve the right to move to a confidential setting should the need arise.

1. Agreed Extension to Motion to Seal Deadlines

Due to the volume of material and the parties' interest in narrowing disagreements as much as possible before bringing any disputes to the Court, the parties jointly request an extension of time to complete the meet-and-confer process and file the motion to seal with respect to materials and exhibits filed in connection with the class certification briefing and Rule 702 briefing on class certification experts. The parties propose that the deadline to meet and confer be extended to July 15, 2022, with the motion to seal to be filed no later than 60 days from the date of the meet and confer. The parties can submit a proposed order reflecting these deadlines subject to the Court's approval.

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2. Plaintiffs' Request for an Expansive Core Discovery Order on Losartan and Irbesartan Prior to Engaging in a Meet and Confer with Defendants

On June 21, 2022, Plaintiffs emailed Defendants a Word document listing discovery items that they believe should be produced by Defendants as "core discovery" with respect to losartan and irbesartan and asking if Defendants wished to meet and confer. (Ex. 1.) Two days later, on June 23, 2022, Defendants responded, asking for Plaintiffs' counsel to identify times to meet and confer and noting that a number of Defendants who did not produce any discovery for valsartan would need to participate given the divergent supply chains and manufacturers for the losartan and irbesartan products. (Ex. 2.) On Monday, June 27, 2022, at 9:32 a.m., Plaintiffs responded and proposed a 1.5 hour window that same day and a 1-hour window on Tuesday, June 28th, for the proposed meet and confer. (Ex. 3.)

Given the number of Defendants who will need to undertake substantial document productions in connection with Plaintiffs' proposal and the limited availability provided, Defendants were not available during the 2.5-hours proposed by Plaintiffs, but have responded and indicated they can be available to meet and confer later this week at a time to be determined. (Ex. 4.) Shortly before the parties were to submit their agenda letters this afternoon, Plaintiffs' counsel indicated they intended to add the losartan and irbesartan core discovery item to the agenda and, moreover, intended to request that the Court enter their Word document as an order at the Wednesday Case Management Conference, despite the lack of a meet and confer on these requests. (Ex. 5.)

As an initial matter, Defendants object to inclusion of this item on the agenda for the CMC prior to the parties engaging in a meet and confer. Defendants responded in two days to Plaintiffs' initial request, which was received less than one week ago, and offered to engage in precisely the type of discussion they believe the Court expects counsel to engage in before bringing these matters to the Court's attention and seeking relief. Nor is there any need to order the parties to meet and confer, as plainly demonstrated by the parties' email correspondence. However, while Defendants would prefer to have had this discussion with Plaintiffs' counsel and ironed out as many minor issues as possible before taking up the Court's time, given Plaintiffs' refusal to remove this item from the agenda for the CMC, we will briefly discuss the types of questions that can and should be the topic of a meet and confer so the parties can propose an order that eliminates the need to revisit the same issues that occupied the Court's time after the valsartan core discovery order was entered in 2019.

First, the request for production of Losartan and Irbesartan ANDA and Drug Master Files ("DMF") is general and does not take into account any subsequent rulings on the relevant timeframe (which was specific to each individual manufacturer of valsartan) or handling of ANDA files that were approved but never marketed in the United States. It does not specify whether ANDAs submitted for approval after the losartan and irbesartan recalls or ANDAs for products that have not yet been approved need to be produced. (*See* ECF No. 303.) Second, the Word document does not specify the format or timing of any productions. As just one example of a prior issue, after the initial core discovery production of valsartan material, Plaintiffs requested and

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Defendants were required to re-produce the same ANDA files they had already produced in eCTD format. If Plaintiffs again prefer production of files in this format and intend to follow with a similar request, Defendants would prefer to discuss and address that possibility now, rather than engage in a costly and ultimately duplicative initial production. Third, while the request for FDA communications and regulatory correspondence largely follows the categories approved for production with respect to valsartan, the Word document again arguably encompasses material that would fall outside of the Court's so-called "macro discovery" order, (*see id.*), and includes a footnote that significantly expands the scope of discovery beyond what was ordered for valsartan. (Compare Ex. 1, with ECF No. 88.) Finally, Plaintiffs' Word document includes a request for production of "All nitrosamine test results," which was not part of valsartan core discovery. While Defendants understand the interest in obtaining these test results and are available to meet and confer over the appropriate scope, the request as drafted could encompass, for example, internal testing performed on non-US product in connection with a not-yet-approved ANDA, which would go beyond any discovery ordered at any time in this litigation, much less as a part of valsartan core discovery.

The above is not intended to be an exhaustive list of the areas where Defendants intend to seek clarification. Indeed, given that the parties have not yet met and conferred, there may be issues of which Defendants are completely unaware. It must also again be emphasized that a number of Defendants who did not engage in valsartan core discovery will be embarking on this process for the first time, and they may have individualized questions or issues that need to be posed to Plaintiffs' counsel. Defendants had hoped to avoid taking up the Court's time with these issues prior to meeting and conferring, and believe most of these items can be resolved and any eventual order drafted to avoid the need to raise these well-known issues with the Court at a later date. However, in light of Plaintiffs' refusal to remove this item from the CMC agenda, Defendants note their strenuous objection to the process and any request to enter Plaintiffs' Word document as an order.

3. PFS Deficiency Issues

Cases Addressed at the June 1, 2022 Case Management Conference:

The Court issued 12 show cause orders returnable at the June 29, 2022 Case Management Conference:

1. *Deborah Harris v. Aurobindo, et al.* – 21-cv-6395
2. *Ulysses Payne v. Camber et al.* – 21-cv-15129
3. *Annie Pace v. Major Pharmaceuticals, et al.* – 20-cv-19170
4. *Donna King v. Doe et al.* – 20-cv-8814
5. *Gail Callahan v. Aurobindo Pharm, Ltd., et al.* – 21-cv-20203
6. *Margaret Tolley v. Mylan Laboratories et al.* – 21-cv-10130
7. *Katherine Peyton v. Mylan et al.* – 21-cv-09063
8. *Michael Shemes v. Aurobindo et al.* – 21-cv-20204
9. *Wayne Grubb v. Aurobindo et al.* – 22-cv-918

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10. *Eric Thompson v. Aurobindo Pharma, et al.* – 21-cv-19973
11. *Mary Richards v. Mylan Laboratories et al.* – 21-cv-17150
12. *Tommy Benton v. Teva et al.* – 21-cv-13858

The issues in the *Grubb*, *Thompson*, *Richards*, and *Benton* matters are resolved, and the show cause orders with respect to those matters may be withdrawn.

The issues in the *Callahan*, *Tolley*, *Peyton*, and *Shemes* matters remain unresolved, but the parties are working towards a resolution and request a one-month extension of these orders to show cause until the July 2022 Case Management Conference.

The issues in the *Harris*, *Payne*, *Pace*, and *King* matters remain unresolved, and Defendants wish to proceed with their dismissal at the CMC.

Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases was previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on June 21, 2022, and a global meet and confer was held on June 24, 2022. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the June 29, 2022 Case Management Conference:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Estate of Leona Branch v. Mylan, et al.	22-cv-582	Levin Papantonio	Need billing records	4/22/22
2.	Vincent Anderson v. ZHP, et al.	22-cv-449	Levin Papantonio	Need billing records	4/22/22
3.	Richard Vindigni v. Princeton, et al.	21-cv-2361	Robert F. Julian	Largely deficient PFS	5/16/22

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
4.	Sheldon Walker v. Aurobindo Pharma, et al.	22-cv-1372	Levin Papantonio	Need billing records	5/16/22
5.	Elie Greene v. Aurobindo Pharma USA, Inc., et al.	21-cv-3214	Serious Injury Law Group	No records or authorizations, sections I.E. & X. are in conflict regarding who completed PFS, plaintiff's purported signature on declaration postdates death by more than a year	5/9/22
6.	E.O. Christopher Gallagher, et al. v. Hetero Labs, Ltd., et al.	22-cv-930	Stark & Stark	Largely deficient PFS	5/17/22
7.	Majorie Smith, as Administrator of E.O. Erskine Smith v. Camber Pharmaceuticals, Inc., et al.	21-cv- 12740	Serious Injury Law Group	Largely deficient PFS	4/19/22
8.	William Davis, as Administrator of E.O. Leila Davis v. Camber Pharmaceuticals, et al.	21-cv- 10767	Serious Injury Law Group	Largely deficient PFS	4/19/22
9.	Ernestine Williams v. Mylan Laboratories Ltd., et al.	21-cv-6946	Douglas and London	Need billing records	04/12/22

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
10.	Marilyn White v. Solco et al.	22-cv-1251	Parafinczuk Wolf	No PFS Filed	5/8/22
11.	Benita King v. ZHP, et al.	22-cv-1628	Levin Papantonio	No PFS Filed	5/23/22

First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiffs' leadership on June 21, 2022, and a global meet and confer was held on June 24, 2022. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Benny Mathis v. ZHP, et al.	22-cv-1246	Hollis Law	Need medical expenses	6/7/22
2.	Estate of John Restivo v. Mylan Laboratories, et al.	22-cv-1442	Chappell, Smith & Arden, P.A.	Need authorizations	6/7/22
3.	Estate of Sebastien Thomas v. ZHP, et al.	22-cv-1247	Hollis Law	Need medical expenses	6/7/22
4.	Estate of Robert Cooper v. ZHP, et al.	22-cv-1635	Levin Papantonio	Need medical expenses	6/7/22
5.	Joseph Martinez v. ZHP, et al.	22-cv-1835	Levin Papantonio	Need updated authorizations	6/16/22

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
6.	Francesco Poma, Individually and o/b/o E.O. Giuseppa Poma v. Hetero Drugs, Ltd., et al.	22-cv-1118	Hollis Law Firm, P.A.	Largely deficient PFS	5/26/22
7.	Kerry Jackson, Individually and o/b/o E.O. Janice Jackson v. Hetero Drugs, Ltd., et al.	22-cv-154	Hollis Law Firm, P.A.	Largely deficient PFS	5/11/2022
8.	Paul Kim v. Mylan et al.	22-cv- 01084	Golomb Spirt Grunfeld	NDC code not reflected in pharmacy records	06/10/22
9.	Joan Chatham v. Mylan et al.		Watts Guerra	Incorrect PFS uploaded	06/10/2022
10.	Raymond Dais v. Mylan et al.	22-cv- 00518	Dennis F. O'Brien PA	Please provide undated authorizations; please provide complete medical expenses	06/15/2022
11.	Estate of Khristian Kay v. Aurobindo, et al.	22-cv-1822	Levin Papantonio	No PFS Filed	PFS Due - 5/31/22
12.	Regina Johnson v. ZHP, et al.	22-cv-1881	Moore Law Group	No PFS Filed	PFS Due - 6/1/22

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
13.	Judith Ross v. Aurobindo Pharma, Ltd., et al.	22-cv-2387	Levin Papantonio	No PFS Filed	PFS Due - 6/26/22
14.	Sandra Russell v. ZHP, et al.	22-cv-2389	Levin Papantonio	No PFS Filed	PFS Due - 6/26/22

Respectfully Submitted,



Jessica Davidson Miller

cc: All counsel of record (via ECF)